SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft procedural guidance entitled ''Guidance Concerning Recommending Customs' Seizure and Destruction of Imported Human and Animal Food That Has Not Been Reconditioned.'' This draft guidance will provide FDA field offices with procedures for recommending seizure and destruction of foods that pose a significant risk to public health.

DATES: Submit written or electronic comments on the draft guidance by January 6, 2003, to ensure adequate consideration of the comments in the preparation of the final guidance. However, you may submit written or electronic comments at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Import Operations and Policy (HFC–170), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request. Submit written comments on the draft guidance to Dockets Management Branch (HFA–305), 5630 Fishers Lane, rm. 1061, Rockville, MD, 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. *See* the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Joseph McCallion, Division of Import Operations and Policy (HFC–170), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–6553, FAX 301–594–3787, email: jmccalli@ora.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In July 1999, the Secretaries of Health and Human Services and Treasury began development of new operational procedures to protect consumers from unsafe imported food. A plan, announced in December 1999, was developed by FDA and the U.S. Customs Service (Customs) to prevent distribution of unsafe imported food by destroying food products that pose a significant risk to public health. This initiative optimizes the statutory authorities and resources available to FDA and Customs.

Food products refused entry into the United States may be offered subsequently for re-importation by importers who choose to circumvent the import regulatory system or by importers who are unaware of the previous refusal. FDA and Customs have worked together on numerous cases to seize and destroy unsafe imported products regulated by FDA. This draft guidance serves to delineate FDA's responsibilities for collecting information, analyzing public health risk, recommending seizure, and coordinating destruction of the violative imported food by Customs. The purpose of this guidance is to ensure that imported food that poses a significant risk to public health is not distributed or exported and subsequently re-entered into U.S. commerce.

The draft guidance entitled ''Guidance Concerning Recommending Customs' Seizure and Destruction of Imported Human and Animal Food That Has Not Been Reconditioned'' is level 1 guidance that is being distributed for comment in accordance with FDA's regulation on good guidance practices (21 CFR 10.115) relating to the development, issuance, and use of guidance documents. The draft guidance represents the agency's current thinking on this topic. It does not create or confer any rights for, or on, any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the draft guidance by January 6, 2003. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.cfsan.fda.gov/~dms/guidance.html*.

Dated: April 5, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–27575 Filed 11–4–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Request for public comment: 60-day proposed information collection.

AGENCY: Indian Health Service.

ACTION: Request for public comment: 60-day proposed information collection.

SUMMARY: The Indian Health Service (IHS), as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) (44 U.S.C. 3506(c)(2)(A)). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the IHS is providing a 60-day advance opportunity for public comment on a proposed new collection of information to be submitted to the Office of Management and Budget for review.

Proposed Collection: Title: 0917–NEW, ''IHS Forms to implement the Privacy Rule (45 CFR parts 160 and 164)''. *Type of Information Collection Request:* New collection. *Form Number(s):* IHS–810, IHS–911, IHS–912–1, IHS 912–2, and IHS 913. *Need and Use of Information Collection:* This collection of information is made necessary by the Department of Health and Human Services Rule entitled ''Standards for Privacy of Individually Identifiable Health Information'' (''Privacy Rule'') (45 CFR Parts 160 and 164). The Privacy Rule implements the privacy requirements of the Administrative Simplification subtitle of the Health Information Portability and Accountability Act of 1996 and creates national standards to protect individual's personal health information and gives patients increased access to their medical records. Sections, 45 CFR 164.508, 522, 526 and 528 of the Rule require the collection of information to implement these protection standards and access requirements. The IHS will use the following data collection instruments to implement the information collection requirements contained in the Rule.

45 CFR 164.508: This provision requires covered entities to obtain or

receive a valid authorization for its use or disclosure of protected health information for other than treatment, payment and healthcare operations. Under the provision individuals may initiate a written authorization permitting covered entities to release their protected health information to entities of their choosing. The IHS–810 will be used to document an individual's authorization to use or disclose their protected health information.

45 CFR 164.522: Section 164.522(a)(1) requires a covered entity to permit individuals to request that the covered entity restrict the use and disclosure of their protected health information. The covered entity may or may not agree to the restriction. The form ''IHS–912–1 Request for Restriction(s)'' will be used to document an individual's request for restriction of their protected health information and whether IHS agreed or disagreed with the restriction. Section 164.522(a)(2)(1) permits a covered entity to terminate its agreement to a restriction if the individual agrees to or requests the termination in writing. The form ''IHS–912–2 Request for Revocation of Restriction(s)'' will be used to document the agency or individual request to terminate a formerly agreed to restriction regarding the use and disclosure of protected health information.

45 CFR 164.526: This provision requires covered entities to permit an individual to request that the covered entity amend protected health information. If the covered entity accepts the requested amendment, in whole or in part, the covered entity must inform the individual that the amendment is accepted and obtain the individual's identification of and agreement to have the covered entity notify the relevant persons with which the amendment needs to be shared. If the covered entity denies the requested amendment, in whole or in part, the covered entity must provide the individual with a written denial. The form ''IHS–911 Request for Correction/Amendment of Protected Health Information'' will be used to document an individual's request to amend their protected health information and the agency's decision to accept or deny the request.

45 CFR 164.528: This provision requires covered entities to permit an individual to request that the covered entity provide an accounting of disclosures of protected health information made by the covered entity. The form ''IHS 913 Request for an Accounting of Disclosures'' will be used to document an individual's request for an accounting of disclosures of their protected health information and the agency's handling of the request.

Completed forms used in this collection of information are filed in the medical record. *Affected Public:* Individuals and households. *Type of Respondents:* Individuals. *Burden Hours:* The table below provides the estimated burden hours for this information collection:

ESTIMATED ANNUAL BURDEN HOURS

45 CFR Section/IHS Form	No. of respondents	Responses per respondent	Burden per response* (minutes)	Total annual burden
164.508 IHS–810	500,000	1	20	166,667
164.522(a)(1) IHS–912–1	15000	1	10	2,500
164.522(a)(2) IHS–912–2	5000	1	10	833
164.526 IHS–911	7500	1	15	1,875
164.528 IHS–913	15000	1	10	2,500
Total Annual Burden		5		174,375

*For ease of understanding, burden hours are provided in actual minutes.

The total estimated burden for this collection of information is 174,375 hours.

There are no capital costs, operating costs and/or maintenance costs to respondents.

Request for Comments: Your written comments and/or suggestions are invited on one or more of the following points: (a) Whether the information collection activity is necessary to carry out an agency function; (b) whether the agency processes the information collected in a useful and timely fashion; (c) the accuracy of public burden estimate (the estimated amount of time needed for individual respondents to provide the requested information); (d) whether the methodology and assumptions used to determine the estimate are logical; (e) ways to enhance the quality, utility, and clarity of the information being collected; and (f) ways to minimize the public burden through the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Send Comments and Requests for Further Information: Send your written comments and requests for more information on the proposed collection or requests to obtain a copy of the data collection instrument(s) and instructions to: Mr. Lance Hodahkwen, Sr., M.P.H., IHS Reports Clearance Officer, 12300 Twinbrook Parkway, Suite 450, Rockville, MD 20852.1601, call non-toll free (301) 443–5938, send via facsimile to (301) 443-2316, or send your E-mail requests, comments, and return address to: *ihodahkw@hqe.ihs.gov.*

Comment Due Date: Your comments regarding this information collection are best assured of having their full effect if received within 60-days of the date of this publication.

Dated: October 28, 2002.

Charles W. Grim,

Assistant Surgeon General, Interim Director.

[FR Doc. 02–28056 Filed 11–4–02; 8:45 am]

BILLING CODE 4160–16–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[WO–310–1310–PB–24–1A]

OMB Approval Number 1004–0–162; Information Collection Submitted to the Office of Management and Budget Under the Paperwork Reduction Act

The Bureau of Land Management (BLM) has submitted a request to the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) to extend a currently approved collection of information listed below. On May 14, 2002, the BLM published a notice in the **Federal**